REMARKS

The Office Action mailed March 13, 2002, has been received and reviewed. Claims 1 through 20 are currently pending in the application. Claims 1 through 20 have been rejected. Applicant has cancelled claims 8, 9 and 11 without prejudice or disclaimer and amended claims 1, 2 and 12 through 16 and respectfully requests reconsideration of the application as amended herein.

Rejections under 35 U.S.C. § 112

Claims 12 through 16 were rejected under the second paragraph of 35 U.S.C. § 112 as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Particularly, the Office noted that the preambles of the subject claims recite a "system", which the Office asserts connotes an apparatus, while the bodies of the subject claims recite methods. *Office Action*, page 2. The preambles of claims 12 through 16 have been amended herein to recite "method" rather than "system". Applicant respectfully submits the subject claims, as amended, satisfy the requirements of the second paragraph of 35 U.S.C. § 112. Accordingly, withdrawal of the rejection is respectfully solicited.

Rejections under 35 U.S.C. § 103(a)

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some **suggestion or motivation**, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a **reasonable expectation of success**. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

Obviousness Rejection of Claims 1 Through 11 Based on U.S. Patent No. 4,054,207 to Lazure *et al.*, in view of Blass *et al.* (Feb. 1991), Stevens *et al.* (Jan./Feb. 1999), Stevens *et al.* (1997), and Franck (2000), and further in view of U.S. Patent No. 3,654,746 to Beckers and U.S. Patent No. 4,597,242 to Hendriks *et al.*

Claims 1 through 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazure et al. (U.S. Patent No. 4,054,207), in view of Blass et al. (Feb. 1991), Stevens et al. (Jan./Feb. 1999), Stevens et al. (1997), and Franck (2000), and further in view of Beckers (U.S. Patent No. 3,654,746) and Hendriks et al. (U.S. Patent No. 4,597,242). Applicant respectfully traverses this rejection, as hereinafter set forth. Claims 8, 9 and 11 have been canceled, without prejudice, rendering the rejection moot as to those claims.

The 35 U.S.C. § 103(a) obviousness rejection of claim 1 as presently amended is improper because there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine reference teachings to arrive at Applicant's invention as claimed. It is respectfully asserted that, contrary to the law, the teaching or suggestion to make the claimed combination is found only in Applicant's disclosure and not in the prior art.

Claim 1, as presently amended, recites:

1. A packaged solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:
a cup-shaped container having a greater width than a depth and defining a cavity therein opening to a mouth;
a volume of a solution comprising sucrose and water within the cavity, wherein the solution comprises about 10% to about 50% sucrose with a remainder of the solution comprising water; and
a cover disposed over the mouth and sealing the solution within the cavity;
wherein the solution and an interior of the container are in an aseptic state. (Emphasis added)

The Office has assembled a combination of references assertedly teaching the aspects of Applicant's invention as claimed in claims 1 through 11. Claim 1, as amended, now recites the specific purpose and aseptic nature of the packaged solution as well as the recipe parameters of the sucrose and water constituents thereof and the general shape of the cup-shaped container in terms of relative width and depth.

Lazure et al., Beckers and Hendriks et al. are cited for the proposition that a sealed, cup shaped container can, as noted by the Office, be used to contain medicine or food. The suitability of using cup-shaped containers to provide unit or individual portions or servings in also asserted, Blass et al., Stevens et al. (1997 and 1999) and Franck (2000) merely teach the use of a sucrose solution in conjunction with medical procedures for infants. Beckers, it is noted, is cited for the additional but general teaching that a cup-shaped container may have a width greater than a depth.

It is respectfully asserted that the combination of references proposed, and the teachings to be gleaned from each, might only be recognized in hindsight from Applicant's own disclosure. Specifically, the present recitation in amended claim 1 of a packaged, aseptic solution of the claimed formulation for use in conjunction with a planned medical procedure on a neonatal infant and disposed in a cup-shaped container having a greater width than a depth could only be motivated by Applicant's own disclosure, as the individual aspects of the recited invention assertedly disclosed in the various references stand in mutual isolation from each other. On the one hand, Lazure et al., Beckers and Hendriks et al. somewhat redundantly teach packaging of various substances in cup-shaped containers, while Blass, Stevens and Franck dwell on the usage and effects of a sucrose solution. However, on the other hand, there is no motivation or suggestion, as required under the law, to make the leap from the prior art practice of batch solution preparation on-site in a hospital kitchen or pharmacy to Applicant's claimed invention of an aseptic, packaged solution in a specifically-configured container related to the purpose of the invention. Accordingly, claim 1 as presently amended is respectfully asserted to be allowable, and the present rejection thereof should be withdrawn.

Claims 2 through 7 and 10 are allowable as depending from claim 1.

Obviousness Rejection of Claims 12 Through 20 Based on Blass *et al.* (Feb. 1991), Stevens *et al.* (Jan./Feb. 1999), Stevens *et al.* (1997), and Franck (2000), in View of U.S. Patent No. 4,054,207 to Lazure *et al.*, U.S. Patent No. 3,654,746 to Beckers, and U.S. Patent No. 4,597,242 to Hendriks *et al.*

Claims 12 through 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Blass *et al.* (Feb. 1991), Stevens *et al.* (Jan./Feb. 1999), Stevens *et al.* (1997), and Franck (2000), and further in view of Lazure *et al.* (U.S. Patent No. 4,054,207), Beckers (U.S. Patent No. 3,654,746) and Hendriks *et al.* (U.S. Patent No. 4,597,242). Applicant respectfully traverses this rejection, as hereinafter set forth.

The Office relies on Blass *et al.*, the two Stevens *et al.* references, and Franck as teaching preparing a solution comprising sucrose and water and administering a selected volume dose of the solution orally to the neonatal infant. *Office Action*, page 4. The Office asserts that claim 12 differs from Blass *et al.*, the two Stevens *et al.* references, and Franck in that the solution is packaged in single use containers and shipped to its intended site of usage. *Id.*

Applicant respectfully submits claim 12 differs from the primary references in at least one additional aspect, namely, the references fail to teach or suggest the claim 12 limitation reciting "discarding any residual solution with the opened, individual, single-use container after the planned medical procedure." This aspect of the claimed method is significant to avoid any potential for cross contamination of other infants. *See* Specification, page 6, lines 2-4. Lazure *et al.*, Beckers, and Hendriks *et al.* fail to expressly teach such discarding, and the Office has not advanced any argument that such discarding is inherent in the secondary references. The obviousness rejection of claim 12 is thus improper because the proposed combination fails to teach or suggest all the limitations of the subject claim. Accordingly, withdrawal of the obviousness rejection as to claim 12 is respectfully solicited.

Applicant respectfully submits claims 13 through 16 are nonobvious because they depend from nonobvious claim 12. MPEP § 2143.03; *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Accordingly, withdrawal of the obviousness rejection as to claims 13 through 16 is respectfully requested.

Applicant further respectfully submits claim 17 is nonobvious for the same reasons as set forth above in relation to claim 12, that is, the combination proposed by the Office fails to teach the claim 17 limitation reciting "discarding any residual solution with the container." Claims 18 through 20, which depend from claim 17, are likewise nonobvious. MPEP § 2143.03.

Accordingly, withdrawal of the obviousness rejection as to claims 17 through 20 is respectfully solicited.

It is further noted that, as set forth above in the context of apparatus claims 1 through 7 and 10, there is no motivation or suggestion in the references to arrive at Applicant's claimed inventive methods. Specifically, and in addition to the "discarding" act noted above, the concept of prepackaging an aseptic sucrose solution for single patient use and administering same is untaught by the prior art, which teaches merely single use packaging and treatment of infants using a sucrose solution in start isolation to one another. Accordingly, claims 12 through 20 are also allowable due to an absence of any suggestion or motivation to combine the references, absent impermissible hindsight reliance on Applicant's own disclosure.

Drawings

Applicant submits herewith formal drawings, under cover of a separate Transmittal of Formal Drawings. Applicant respectfully requests approval of the formal drawings.

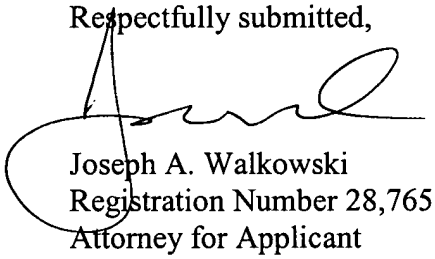
Entry of Amendments

The amendments to claims 1, 2 and 12 through 16 above should be entered because the amendments are supported by the as-filed specification and drawings and add no new matter to the application

CONCLUSION

Claims 1 through 7, 10 and 12 through 20 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain that might be resolved most expeditiously by a telephone interview, he is respectfully invited to contact Applicant's undersigned attorney.

Respectfully submitted,



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Enclosure: Version With Markings to Show Changes Made

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice Amended) A packaged solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:

a cup-shaped container having a greater width than a depth and defining a cavity therein opening to a mouth;

a volume of a solution comprising sucrose and water within the cavity, wherein the solution comprises about 10% to about 50% sucrose with a remainder of the solution comprising water; and

a cover disposed over the mouth and sealing the solution within the cavity;

wherein the solution and an interior of the container are in an aseptic state.

2. (Amended) The packaged solution of claim 1, wherein the cover includes a lateral protrusion extending beyond a lateral extent of the cup shape of the container.

12. (Twice Amended) A [system]method for providing a solution for use in conjunction with a planned medical procedure on a neonatal infant, comprising:

preparing a solution comprising sucrose and water;

packaging the solution in single-use containers;

assembling a plurality of the single-use containers in a shipping container;

shipping the shipping container to an intended site of usage of the solution;

opening an individual, single-use container of the solution prior to the planned medical procedure;

administering a selected volume dose of the solution orally to the neonatal infant; and

discarding any residual solution with the opened, individual, single-use container after the planned medical procedure.

13. (Twice Amended) The [system of]method according to claim 12, further comprising maintaining the solution in each single-use container in an aseptic state after packaging until opening thereof for the planned medical procedure.

14. (Twice Amended) The [system of]method according to claim 12, further comprising packaging the solution in cup-shaped, single-use containers having covers sealed over mouths thereof.

15. (Amended) The [system of]method according to claim 12, further comprising formulating the solution to comprise between about 10% and about 50% sucrose with a remainder of the solution comprising water.

16. (Amended) The method [of]according to claim 12, further comprising formulating the solution to comprise about 24% USP grade liquid sucrose to 76% clean water.